

(7) A vaginal applicator is an instrument used to insert medication into the vagina.

(8) A vaginal retractor is an instrument used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue.

(9) A gynecological fibroid hook is an instrument used to exert traction upon a fibroid.

(10) A pelvimeter (external) is an instrument used to measure the external diameters of the pelvis.

(b) *Classification.* Class I (general controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 54 FR 25052, June 12, 1989; 66 FR 38809, July 25, 2001]

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

(a) *Identification.* An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance. This type of device consists of the following:

(1) An amniotome is an instrument used to rupture the fetal membranes.

(2) A circumcision clamp is an instrument used to compress the foreskin of the penis during circumcision of a male infant.

(3) An umbilical clamp is an instrument used to compress the umbilical cord.

(4) A uterine curette is an instrument used to scrape and remove material from the uterus.

(5) A fixed-size cervical dilator is any of a series of bougies of various sizes used to dilate the cervical os by stretching the cervix.

(6) A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus.

(7) A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination.

(8) A cervical cone knife is a cutting instrument used to excise and remove tissue from the cervix.

(9) A gynecological cerclage needle is a looplike instrument used to suture the cervix.

(10) A hook-type contraceptive intra-uterine device (IUD) remover is an instrument used to remove an IUD from the uterus.

(11) A gynecological fibroid screw is an instrument used to hold onto a fibroid.

(12) A uterine sound is an instrument used to determine the depth of the uterus by inserting it into the uterine cavity.

(13) A cytological cervical spatula is a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina.

(14) A gynecological biopsy forceps is an instrument with two blades and handles used for gynecological biopsy procedures.

(15) A uterine tenaculum is a hook-like instrument used to seize and hold the cervix or fundus.

(16) An internal pelvimeter is an instrument used within the vagina to measure the diameter and capacity of the pelvis.

(17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina.

(18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

§ 884.4550 Gynecologic surgical laser.

(a) *Identification.* A gynecologic surgical laser is a continuous wave carbon dioxide laser designed to destroy tissue